



Military Medical Research News

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Journal editors weigh in on how to get published Insiders share insights on do's, don'ts of manuscript submission

by Paula Amann

Dottie Roberts, the editor of MEDSURG Nursing, recalls two standout papers she accepted for publication in her journal. One, co-written by a doctoral student and her professor, considered how to provide respectful care for Muslim women patients. Another discussed how to spot pressure ulcers, also known as bed sores, among dark-skinned patients – “a topic that needed a podium,” Roberts said.

When journal editors like Roberts sift through the manuscripts in their inbox, they are seeking, above all, originality. “A new perspective, a new way to look at an old problem” is what Roberts said she hopes to find.



Army Col. Dr. Peter J. Weina, chief of the Department of Research Programs, holds a quote from the late Sen. Robert F. Kennedy that Weina keeps taped on a wall of his office: “Only those who dare to fail greatly can ever achieve greatly.” Weina cites this remark to encourage researchers to submit their work to medical journals and help grow the field of medicine. (Photo by Paula Amann)

To her search for the next innovative study Roberts brings a long career in both nursing and research. A clinical nurse specialist since 1996, she has served as executive director of the Orthopaedic Nurses Certification Board since 2005 and is also the accreditation manager of the Accreditation Board for Specialty Nursing Certification.

For Army Lt. Col. Dr. Benjamin “Kyle” Potter, “a bounty of qualified manuscripts” is an editor’s dream, which can grow a journal’s audience, even as these studies also stretch the boundaries of knowledge.

“If you have more readership, volume and hits on your journal, that’s good for medical science and good for your journal,” said Potter, who is the deputy editor of Clinical Orthopaedics and Related Research, as well as associate editor of the Journal of Orthopaedic Trauma and the Journal of Surgical Orthopaedic Advances.

Potter is also the chief of Orthopaedic Surgery at Walter Reed Bethesda and a professor in the Department of Surgery at the Uniformed Services University of the Health Sciences.

Along with editors like Potter and Roberts, section editors, editorial board members and reviewers also help shape what gets published in journals.

For example, Army Col Dr. Peter J. Weina, the chief of the Department of Research Programs at Walter Reed National Military Medical Center, serves on the board of the Canadian Journal of Infectious Diseases and Medical Microbiology.

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DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center supports research activities in the National Capital Region (NCR) through regular news.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other NCR initiatives.

MILITARY MEDICAL RESEARCH NEWS

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). Please send any timely information by the 15th day of the prior month for the following month's issue. Send your ideas, pictures or infographics to paula.m.amann.ctr@mail.mil.

RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission. To make an appointment with a protocol navigator, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

RESEARCH ROUNDTABLE SCHEDULE

Walter Reed National Military Medical Center

America Building (Building 19), Second floor, Room 2301

- ◆ Tuesday, April 18, 1200-1300
- ◆ Tuesday, June 20, 1200-1300

Did you miss the last roundtable? Please see story on page 9. In light of Research and Innovation Month, there will be no roundtable in May.

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EIRB TIP OF THE MONTH

Ensuring a Clean Copy

Cutting and pasting? Avoid potential errors when transferring a Microsoft Word document into the text editors in the electronic Institutional Review Board system, or EIRB.

If you are cutting or copying from a Word document to insert text into your EIRB Protocol Application or other forms using a Text Box Editor, use the buttons on the toolbar of the Text Box Editor. Do not use the "Control V" function.

Using the toolbar buttons will remove any unwanted "macros" or other unwanted ill affects attached to the original document. If this is not done, there is no guarantee that the PDF version created when printing the document will be a correct copy of the intended document.

When printing any document, first save it as an HTML copy. Then print it to PDF by using the Print to PDF option in the print dialogue box.

Thanks again for your patience during this past year's transition to EIRB. Meanwhile, our best wishes for a great month of research.



COMMAND CORNER

The Hows and Whys of Overhead

I want to take this opportunity to address the 'new' indirect overhead for industry-sponsored research performed at Walter Reed Bethesda. Actually, this is not a new concept, but has been a work in progress since June of 2014.

We are required by Department of Defense Instruction (DoDI) 6000.08 (22Jan2014) to recoup costs associated with research. The DoDI states: "All research activities and CIs using DHP funds must ensure procurement contracts, grants, and cooperative agreements for DHP-funded awards that provide for the use of MHS facilities, include in their award budgets appropriate reimbursement for direct and indirect costs to such facilities." There are other instructions such as DoDI 7000.14-R (Financial Management Regulation; General Reimbursement Procedures and Supporting Documentation), DoDI 4000.19 (Support Agreements) and the Assistance/Procurement Advisory Notice 15-01 that require us to recuperate costs associated with doing research in our facility.

The percentage overhead we use is provided by the hospital's Comptrollers Office, which independently calculated the cost of doing research here. The actual memorandum that orders the use of this rate for industry-sponsored research was signed by the hospital chief of staff. These funds are returned to the hospital to recuperate the cost of this research. This is important since tens of millions of dollars are required every year to support research at this facility, and to date these funds have come out of patient care dollars.

I hope this addresses the principal questions related to this overhead. If there are questions about research practices at Walter Reed Bethesda, please feel free to contact me directly for answers.

Army Col. Peter J. Weina

DEPARTMENT ANNOUNCEMENTS

Determinations made plain

Got a great project idea? We've made getting your determination letter easier than ever. Launch your quality improvement, performance improvement, Lean Six Sigma or evidence-based practice project with our new template. We've even provided a guide for navigating your submission to the electronic Institutional Review Board (EIRB).

Find it all at the top of the intranet home page for the Department of Research Programs. Click on the orange tab at the top that says, "Plan research, QI, PI, EBP or LSS project."

Major research events set for next month

In May, the Department of Research Programs is hosting Research and Innovation Month, with a series of events open to all. Over the first week of May, you can view posters in Arrowhead (Building 9). Participants from Walter Reed National Military Medical Center and partner groups will present in front of their posters on May 3 from 10 a.m. to 4 p.m. These finalists will vie for Evidence-Based Practice, Quality Improvement and Case Report Awards.

Another set of finalists will compete on May 4 from 11 a.m. to 2 p.m. for the Paul Florentino Patient- and Family-Centered Care Award, also in Building 9. Patients and family members are welcome. Refreshments, including dessert, will be served.

On May 9-10 in Memorial Auditorium, the month's Research Symposia will run from 8 a.m. to about 3 p.m. each day. Selected finalists and winners for awards in research, case reports, patient- and family-centered care, evidence-based practice and quality improvement will present slides of their work and receive awards.

Mid-month, Aware for All, a celebration of military medical research, will take place on May 16 from 11 a.m. to 2 p.m. in the lobby of the America Building (Building 19). Groups will display their research and offer participation opportunities to those interested.

Designed for networking and information sharing, Spring Research Summit will take place in the Memorial Auditorium (Building 2) on May 24, from about 8 a.m. to 2 p.m. Speakers will present on topics ranging from ongoing research to funding and opportunities for collaboration. Please join us for any and all of these events. ▣



TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department. Or join our monthly classes. We have only eight spaces per class, so sign up today!

Your Monthly Class

Find it in Heroes Building (Building 5), fourth floor:

- May 8, 2-3 p.m., Computer Classroom 2 (4011)

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.



You belong in the CITI. Start training today!

Interested in data analysis?

Let the biostatistics team at the Department of Research Programs help. With two weeks' notice, we can lecture on many topics for you and five or more people:

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?

Contact Ms. Sorana Raiciulescu at sorana.raiciulescu.ctr@mail.mil



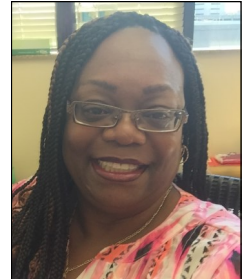
HOT TOPICS IN COMPLIANCE

Is an Investigator's Self-Assessment a regulatory requirement?

by Diane Beaner, compliance officer

Answer: No, but it's highly encouraged.

The Investigator's Self-Assessment is highly encouraged but is not a regulatory requirement. In light of recent changes to research policies and practices, the Post-Approval Compliance Monitoring team now recommends that a principal investigator and the research staff conduct self-assessments of their research. The intent of collecting assessments is not punitive. Rather, they serve as accountability tools for investigators, help the compliance team respond to investigator needs, and document internal monitoring.



Diane Beaner, research compliance officer
(Photo by subject)

Frequently Asked Questions

1. What is an Investigator's Self-Assessment?

The Investigator's Self-Assessment is a checklist that can help researchers maintain and organize study documentation (i.e., regulatory documentation and participant files) and ensure compliant study practices.

2. Why should I complete an Investigator's Self-Assessment?

The Investigator's Self-Assessment serves as a guide to assess whether regulatory documentation and participant files are complete and well-organized. The self-assessment serves to provide an internal measure of compliance.

3. Why complete an assessment for this protocol, when I've completed a self-assessment on another protocol within the past year?

Despite their name, self-assessments relate to protocols, rather than the people who conduct them. Please keep in mind that the self-assessment checklist is a tool to help monitor and keep records for each study. In fact, researchers should monitor their studies regularly to ensure compliance.

4. How do I complete an Investigator's Self-Assessment?

Review your regulatory documentation using the Investigator's Self-Assessment. Simply check off which documents you currently have in your research files. Once you have completed the checklist, please share the results with your entire study team.

Is your project a clinical research study?

If your study involves clinical research — including [an investigational new drug \(IND\) or investigational device exemption \(IDE\)](#) — please also complete the applicable section of the Investigator Self-Assessment. Answer all questions as they pertain to study documentation maintained in your regulatory files and provide confirmation of your study conduct.

Does your study have subject files?

Complete the subject file assessment of the self-assessment if you have direct access to subject files. Feel free to have study staff who maintains subject files on site complete the checklist if desired. It is not necessary to review every subject file for the purposes of this self-assessment. We recommend randomly sampling approximately 10 subject files, though you can review more at your discretion.

5. Do I need to have curriculum vitae and training records on file for everyone involved in the study?

It is best practice to have curriculum vitae (CVs) and training records for every staff member. If they are kept separately from your regulatory files or in electronic files, write a note in the file indicating where these records are kept. As part of best practice, CVs should be updated, signed and dated every three years. Updated CVs must be maintained when a protocol is required to follow [International Conference on Harmonisation Good Clinical Practice \(ICH GCP\)](#).

Final thoughts

Every research study should maintain IRB documentation on file to verify that regulatory requirements to conduct research are met. Some studies may choose to maintain regulatory documentation electronically or on paper. In either case, documentation should be organized and accessible in such a way that an outside auditor can view it easily and securely without violating privacy, confidentiality and data access requirements. □



EDITORS, from page 1

Weina also regularly reviews articles for journals such as *Lancet*, *American Journal of Tropical Medicine and Hygiene*, *Transactions of the Royal Society of Tropical Medicine & Hygiene*, *Clinical Infectious Diseases*, and *Emerging Infectious Diseases*.

Each publication has a distinct readership, Weina stressed, and a savvy researcher will bear that in mind when submitting a manuscript. For example, a clinical study doesn't belong in a journal that deals with basic science.

"Applicability to the audience is exceedingly important," said Weina.

What prompts the early discard of a manuscript? Potter flagged poorly planned research as his top reason to reject a paper. The problem often lies in a rushed, last-minute design of the research question, he noted.

"When you formulate your question in a post hoc fashion, you are not answering the question you set out to," said Potter. "You're conveying the answers you stumbled upon."

In his experience, a vague title or subtitle, such as "The Walter Reed Experience," also can alert the editor or reviewer that the authors were slipshod in their research design.

For retired Army Col. Dr. Chester "Trip" Buckenmaier III, a section editor for *Pain Medicine*, the reason for rejection most often lies in sloppy spelling, grammar and syntax.

"The science could be really interesting, but could be destroyed by the writer's inability to form a clear sentence," said Buckenmaier, the director of the Defense and Veterans Center for Integrative Pain

'You should submit something that's publication ready. You make the editor's job easier, the reviewer's job easier and the copyeditor's job easier, and you're more likely to get your manuscript accepted.'

— Army Lt. Col. Dr. Benjamin
"Kyle" Potter

Management at the Uniformed Services University of the Health Sciences (USU).

As a result, Buckenmaier, who is also a professor in the Department of Military and Emergency Medicine at

USU, urges significant pre-editing prior to manuscript submission.

"Have an editor check for language," Buckenmaier said, "and have another editor [who] can help with the structure of the manuscript."

Other publication insiders echo the need for clear, correct writing in the style called for by the journal's guidelines. If

researchers' prose is "sloppy and shoddy," suggested Weina, "it's an indication of how they may have performed their research."

As for Potter, he views overuse of the passive voice and split infinitives as signals of poor writing to come.

"You should submit something that's publication ready," Potter said. "You make the editor's job easier,

the reviewer's job easier and the copyeditor's job easier, and you're more likely to get your manuscript accepted."

Upon receiving a new submission, Weina says he first checks its scholarly references, searching for recent articles on similar topics in a major medical research database such as PubMed. If the authors of a manuscript fail to cite them, Weina said, "that's an almost immediate reject."

"When research is done correctly, before you've even done the study, you've read the literature," Weina said.

Without deeply knowing the field, researchers cannot identify a gap in



Retired Army Col. Dr. Chester "Trip" Buckenmaier III, director of the Defense and Veterans Center for Integrative Pain Management at Uniformed Services University of the Health Sciences, where he is also a professor. (Photo courtesy of USU)

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EDITORS, from page 6

knowledge worth exploring, nor can they assess the significance of any findings from the research, he explained.

Every section of a manuscript has its pitfalls, suggested the editors interviewed for this story.

For Potter, the weaknesses of a study often emerge in an abstract that simply does not make sense. This journal editor reads that opening summary before and after reviewing the full submission.

“It’s a big red flag for the reader if your results don’t flow from your methods, and your conclusions don’t flow from your results,” Potter said.

Buckenmaier often finds problems in the discussion section, where researchers grapple with the meaning of their results.

“Overstating the importance or conclusiveness of the data is a common error,” Buckenmaier said.

Novice researchers, he cautioned, have a tendency to claim more than their findings can justify.

“Grandiose studies like the double helix by Watson and Crick are really rare,” Buckenmaier said, referring to the 1953 study by biologists James Watson and Francis Crick that revealed the shape of the DNA molecule.

When Roberts scans a manuscript, she keeps a sharp eye out for trouble in the design of the methods section. Too many research projects, in her experience, collect quantitative data from a small sample of patients, making the ultimate findings carry less weight than they might otherwise.

Roberts also reported seeing a lot of studies that fail to establish how their findings actually impact the everyday business of nursing.

“How is the reader going to use the information in the article in his or her practice?” Roberts asked rhetorically.

She noted that she expects her authors to provide a strong statement in the Nursing Implications section required by her journal.

For his part, Potter has found two major issues that tend to surface in the results section of a paper.

At one end of the spectrum is the “data dump,” in which some researchers pack too much material into the section, rather than relying on tables and appendices for large amounts of data.

“A table is worth 1,000 words,” Potter said.

On the other hand, other researchers resort to what he calls “salami slicing” by sharing only a minimum of their data in a given paper, in an effort to get their work on the same project published in multiple journals.

The final section of most articles, references, may seem like an afterthought to some researchers, but it’s important to craft it thoughtfully, with a focus on the most recent studies, opined Roberts.

“We need a literature review within the last three to five years to identify the gap in the literature they [researchers] purport to address,” Roberts said.

Meanwhile, the journal editors and reviewers interviewed want to know what an investigator actually learned, even if it means publishing negative results, said Weina and Buckenmaier.

“The journey of discovery in science is 1,000 false pathways,” Weina said. “The task is to eliminate the false paths.”

What’s more, researchers who illuminate the wrong way to solve a problem actually help those following behind them, stressed Buckenmaier.

“Every failure is a secret success, because that’s an avenue we don’t have to try again,” Buckenmaier said.



Dottie Roberts edits MEDSURG Nursing, the journal of the Academy of Medical-Surgical Nurses. (Photo courtesy of the Orthopaedic Nurses)

See EDITORS, page 8



Writing Rx

Free Editorial Services

Department of Research Programs

- * ***Set up a private writing consultation.***
- * ***Get a professional edit of your manuscript.***
- * ***Hold a training to boost your team's writing skills.***



Reach out to a friendly editor.

Email paula.m.amann.ctr@mail.mil.

EDITORS, from page 7

For health care professionals, finding time to do trail-blazing research alongside their clinical and administrative tasks may seem daunting. Yet, generating new science can help inform crucial conversations with patients, while, at the same time, expanding medical knowledge.

“Part of our goal is not only to educate our patients but the next generation of doctors,” Buckenmaier said. “We have an obligation to pass on what we’ve learned but also contribute to it.”



Army Lt. Col. Dr. Benjamin “Kyle” Potter is deputy editor of *Clinical Orthopaedics and Related Research*, and associate editor of the *Journal of Orthopaedic Trauma* and the *Journal of Surgical Orthopaedic Advances*. (Photo courtesy of USU)

For those averse to research, there are other ways to contribute to medicine, said Buckenmaier and Potter, who noted that journals are often seeking expert reviewers to help vet manuscript submissions.

“There is huge value in being a reviewer for a couple of journals, because it will make you a better clinician,” Potter said.

A physician or nurse who regularly reviews research studies can better interpret the medical literature and thereby help their patients, he suggested.

Some observers might view doing medical research and submitting it to journals as a cerebral enterprise, but it also takes courage, suggests Weina. He calls this work “wrestling with the field,” and he sees it as essential.

“The only way to really understand something is to become engaged in it,” said Weina.

He pointed to a quote from President Theodore Roosevelt that hangs in Weina’s office and echoes the combat metaphor.

“The credit belongs to the man who is actually in the arena,” Roosevelt said in a 1910 speech, contrasting the person who “at least fails while daring greatly” with “those cold and timid souls who neither know victory nor defeat.”

As for potential researchers shy about venturing into the arena and submitting their results to a medical journal, Weina has yet another quote. This one comes from the late Sen. Robert F. Kennedy: “Only those who dare to fail greatly can ever achieve greatly.”

“If you don’t fail occasionally,” Weina said, “you’re not reaching your full potential.” □



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff. Our talk ranges from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [(Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF) issued by the Office of the Assistant Secretary of Defense for Research and Engineering, and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements.

Our services include assistance with protocol development, courses on research methods, statistics, and grant writing, GME trainee research project funding opportunities, collaborative agreements development, manuscript editing, publication clearance, and bench research space through our Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable on the third Tuesday of most months at noon. Given the wealth of events for Research and Innovation Month in May, though, we will omit the roundtable in May. Please rejoin us on June.20.

We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to present material on a topic of your choice, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil. □



Lisa Thompson,
supervisory medical
education specialist
(Photo by subject)



Binder reminders are theme of March Roundtable Beaner details ins and outs of essential documents

by Paula Amann

For researchers at Walter Reed Bethesda, regulatory binders remain a must. That insistence on thorough record keeping – whether in physical or electronic form – was a



Diane Beaner, research compliance officer for the Department of Research Programs, makes a point at the March 21 Research Roundtable. (Photo by John Fadoju)

recurring theme of the Research Roundtable on March 21.

“Store your binder in a secure location, and make it accessible to staff at all times,” said

the month’s speaker, Diane Beaner, research compliance officer with the Department of Research Programs.

Maintaining crucial documents is essential to ethical research, suggested Beaner. Furthermore, she counseled researchers to review their regulatory binder for regulatory binder for completeness and accuracy at least once or twice a year.

“If it’s not documented, it didn’t happen,” she said.

Essential documents include such items as protocols, correspondence and safety reports. Their collection, said Beaner, “holds you to a standard of good clinical practice, which is critical to compliance.”

See BINDER, p. 10



BINDER, from page 9

For lists of exactly what to keep, Beaner pointed to the International Conference on Harmonisation Good Clinical Practice (ICH GCP).

As the Department of Research Programs updates its intranet home page, Beaner hopes to make this guidance easier to find online for the research community.

In general, Beaner suggested grouping documents by time of use: before, during, and after the study. See accompanying sidebar for a detailed list.

Meanwhile, she cautioned that researchers must keep outdated or expired documents, such as protocols, investigator brochures, and the like.

In fact, protected health information, or PHI, must be kept for six years and all other study records for three years.

Meanwhile, the U.S. Food and Drug Administration requires keeping records for two years after approval of an investigational product or withdrawal of an investigational new drug (IND) or investigational device exemption (IDE).

“If you were to get rid of old materials, you would be out of compliance,” Beaner said.

However, researchers are free to archive such outdated documents, separate from the main regulatory binder.

As for research subject data, she advised housing that material in a file separate from other regulatory documents.

“Anything with participant IDs should be kept outside of the binder,” Beaner said. ▣

Protected health information, or PHI, must be kept for six years and all other study records for three years.

Quick Guide to the Regulatory Binder

Whether your research team houses all documents online or in a sturdy binder, you will need to divide materials into three broad categories: before, during and after your study. A list of required items follows:

Before your study

- Protocol, as approved by the Institutional Review Board (IRB)
- Human subject consent forms
- Health Insurance Portability and Accountability Act (HIPAA) forms
- Copy of case report form (CRF) or data collection sheet
- IRB approval letter and other correspondence
- Advertisement for recruitment (if used)
- Financial agreements and financial disclosure form (if applicable)
- Investigator drug brochure or device manual and FDA form 1572 (if applicable)
- Curriculum vitae and training records
- Delegation of responsibilities log
- Other investigational product materials (if applicable)
- Other signed agreements (if applicable)

During your study

- Revised protocols and any amendments, and CRF
- Consent forms
- Participant enrollment/screening log
- Participant identification code list
- Advertisements (if used)
- Updates to investigator drug brochure or device manual
- On-going IRB Approval letters
- Curriculum vitae (CVs) and training records for new investigators
- Monitoring visit reports
- Other communications/correspondences
- Safety reports/Unanticipated Problem and Protocol Deviation Reports
- Investigational product accountability log with shipping receipts

After your study

- Investigational product accountability log with shipping receipts at site (if applicable)
- Documentation of investigational product destruction (if applicable)
- Close-out study reports
- Close-out monitoring report (if applicable)
- Completed subject identification code list
- Treatment allocation and decoding list (if applicable) ▣



FACES OF RESEARCH

ARRIVAL GATE

Originally from Houston, Texas, **Pfc. Dan Lewis** joined the U.S. Army in May 2015. Lewis did his basic training at Ft. Benning, Georgia.

He started advanced individual training at Ft. Sam Houston in Texas and completed it at Walter Reed Bethesda. Becoming a medical laboratory technician, he remained at Walter Reed Bethesda for his first duty station.

When he got the opportunity to work in the Biomedical Research Laboratory, Lewis accepted the position. Eventually, he hopes to become an agent in the Criminal Investigation Department and assume the position of a warrant officer.



Pfc. Dan Lewis (Photo by Paula Amann)

GOODBYE AND GOOD LUCK

After two years at the helm of the Education, Training and Research Directorate, **Col. Brian Belson** will likely be moving on to a new post at Walter Reed Bethesda in mid-April. He will be capping a long and varied career in Army, Navy and civilian medicine.

Belson grew up in Manitowoc and Green Bay, Wisconsin, and earned a bachelor's degree at the University of Wisconsin at River Falls. He went on to Creighton University in Omaha, Nebraska, first in the School of Pharmacy and then the School of Medicine, under the Health Professions Scholarship Program, after receiving a commission as a U.S. Navy ensign.



Col. Brian Belson (Photo by Paula Amann)

After his medical school graduation and promotion to lieutenant, Belson received a civilian deferment for a transitional year internship at St Joseph's Hospital in Omaha. Afterwards, he was accepted into the Navy Flight Surgery program in Pensacola, Florida, where he completed the rotary wing syllabus and graduated with his flight surgeon wings.

Completing his three-year tour in Hawaii and Oklahoma, Belson did a residency in obstetrics and gynecology at Naval Medical Center San Diego. Another tour in Pensacola ended with his entering private practice in Wisconsin.

After a couple of years in private practice, Belson said he missed the excitement and challenge of military medicine. As a result, he accepted a direct commission into the U.S. Army in 2002, which allowed him to again work with medical students and residents.

His first duty assignment was Walter Reed Army Medical Center in Washington, D.C. There he headed the Gynecology Division, served as army associate program director, assistant department chief, and acting department chief for Obstetrics and Gynecology. After the launch of Walter Reed National Military Medical Center, Belson served as deputy director for Education, Training, and Research (ETR) before becoming its director.

During his Army service, Belson has supported mission-essential temporary duties from South Korea to Michigan and Louisiana. He first deployed to Iraq as chief of surgery for the 10th Combat Support Hospital in Tallil, Iraq. More recently, he was chief of clinical operations and deputy commander of clinical services for the 28th Combat Support Hospital in Kandahar and Bagram, Afghanistan.



RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

- Andreini D, Pontone G, Mushtaq S, et al. [Long-term prognostic impact of CT-Leaman score in patients with non-obstructive CAD: results from the Coronary CT Angiography Evaluation For Clinical Outcomes International Multicenter \(CONFIRM\) study](#). *Int J Cardiol*. 2017;231:18-25. Walter Reed Bethesda author: **Villines TC**
- Becker WC, **Dorflinger L**, Edmond SN, Islam L, Heapy AA, Fraenkel L. [Barriers and facilitators to use of non-pharmacological treatments in chronic pain](#). *BMC Fam Pract*. 2017;18(1):41.
- Bedigrew KM, Stinner DJ, Kragh JF Jr, **Potter BK**, **Shawen SB**, Hsu JR. [Effectiveness of foot fasciotomies in foot and ankle trauma](#). *J R Army Med Corps*. 2017 Mar 23. [Epub ahead of print]
- Brietzke SE**, Ishman SL, Cohen S, Cyr DD, Shin JJ, Kezirian EJ. [National database analysis of single-level versus multilevel sleep surgery](#). *Otolaryngol Head Neck Surg*. 2017 Mar 1. [Epub ahead of print]
- Bruns BR, Morris DS, Zielinski M, et al. [Stapled versus hand-sewn: a prospective emergency surgery study. An American Association for the Surgery of Trauma multi-institutional study](#). *J Trauma Acute Care Surg*. 2017;82(3):435-443. Walter Reed Bethesda author: **Oh JS**
- Cheezum MK, Liberthson RR, Shah NR, et al. [Anomalous aortic origin of a coronary artery from the inappropriate sinus of valsalva](#). *J Am Coll Cardiol*. 2017;69(12):1592-1608. Walter Reed Bethesda author: **Villines TC**
- Chung EM, **Soderlund KA**, **Fagen KE**. [Imaging of the pediatric urinary system](#). *Radiol Clin North Am*. 2017;55(2):337-357.
- Colborn VA, LaCroix JM, Neely LL, et al. [Motor impulsivity differentiates between psychiatric inpatients with multiple versus single lifetime suicide attempts](#). *Psychiatry Res*. 2017;253:18-21. Walter Reed Bethesda author: **Grammer G**
- Dziki JL, Giglio RM, Sicari BM, et al. [The effect of mechanical loading upon extracellular matrix bioscaffold-mediated skeletal muscle remodeling](#). *Tissue Eng Part A*. 2017 Mar 27. [Epub ahead of print] Walter Reed Bethesda author: **Deearth CL**
- Elliott EJ**, Landaker EJ. [Worsening migraine due to neurocysticercosis](#). *Cleve Clin J Med*. 2017;84(3):196-198.
- Golyski PR**, **Hendershot BD**. [A computational algorithm for classifying step and spin turns using pelvic center of mass trajectory and foot position](#). *J Biomech*. 2017;54:96-100.
- Grasso IA**, **Blattner MR**, Short T, Downs JW. [Severe systemic lead toxicity resulting from extra-articular retained shrapnel presenting as jaundice and hepatitis: a case report and review of the literature](#). *Mil Med*. 2017;182(3):e1843-e1848.
- Griffis CE, Olsen C, **Nesti L**, **Gould CF**, **Frew M**, **McKay P**. [Validity of computed tomography in predicting scaphoid screw prominence: a cadaveric study](#). *Arch Orthop Trauma Surg*. 2017 Mar 4. [Epub ahead of print]
- Hammer D**, Rendon JL, **Sabino J**, **Latham K**, **Fleming ME**, Valerio IL. [Restoring full-thickness defects with spray skin in conjunction with dermal regenerate template and split-thickness skin grafting: a pilot study](#). *J Tissue Eng Regen Med*. 2017 Mar 22. [Epub ahead of print]
- Harrop JS, **Rymarczuk GN**, Vaccaro AR, Steinmetz MP, Tetreault LA, Fehlings MG. [Controversies in spinal trauma and evolution of care](#). *Neurosurgery*. 2017;80(3S):S23-S32.
- Heitmann RJ**, Hill MJ, **Csokmay JM**, **Pilgrim J**, DeCherney AH, Deering S. [Embryo transfer simulation improves pregnancy rates and decreases time to proficiency in Reproductive Endocrinology and Infertility fellow embryo transfers](#). *Fertil Steril*. 2017 Mar 11.[Epub ahead of print]
- Henry JL**. [A transgender military internist's perspective on readiness for treating patients with gender dysphoria](#). *JAMA Intern Med*. 2017 Mar 13. [Epub ahead of print]
- Hernandez CL**, Waibel KH, Kosisky SE, **Nelson MR**, **Banks TA**. [15 years of allergen immunotherapy vial sterility testing](#). *Ann Allergy Asthma Immunol*. 2017;118(3):374-375.
- Junga Z**, **Stratton A**, **Laczek J**. [Primary multifocal small bowel follicular lymphoma discovered incidentally on diagnostic endoscopy](#). *Clin Gastroenterol Hepatol*. 2017 Mar 11. [Epub ahead of print]
- Kang DG, Lehman RA Jr, **Wagner SC**, Peters C, Riew KD. [Outcomes following arthrodesis for atlanto-axial osteoarthritis](#). *Spine (Phila Pa 1976)*. 2017;42(5):E294-E303.
- Kapural L, Gilmore CA, Chae J, et al. [Percutaneous peripheral nerve stimulation for the treatment of chronic low back pain: two clinical case reports of sustained pain relief](#). *Pain Pract*. 2017 Mar 14. [Epub ahead of print]
- Walter Reed Bethesda author: **Cohen SP**
- Kucera WB**, **Jeziro JR**, **Duncan JE**. [Management of post-traumatic rectovesical/rectourethral fistulas: case series of complicated injuries in wounded warriors and review of the literature](#). *Mil Med*. 2017;182(3):e1835-e1839.

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PUBLICATIONS, from page 12

- Lande RG, Pierce J.** [Efficacy of transcranial magnetic stimulation for treatment resistant depression among active duty service members](#). *Gen Hosp Psychiatry*. 2017;45:99-100.
- Lane I, Stockinger Z, Sauer S, et al. [The Afghan theater: a review of Military Medical Doctrine from 2008 to 2014](#). *Mil Med*. 2017;182(S1):32-40. Walter Reed Bethesda author: **Bailey J**
- Lee J, Jackman JG, Kwun J, et al. [Nucleic acid scavenging microfiber mesh inhibits trauma-induced inflammation and thrombosis](#). *Biomaterials*. 2017;120:94-102. Walter Reed Bethesda author: **Elster EA**
- Lee MA**, McGlinch EB, McGlinch MC, **Capacchione JF**. [Malignant hyperthermia susceptibility and fitness for duty](#). *Mil Med*. 2017;182(3):e1854-e1857.
- Lutgendorf MA, Snipes MA, **O'Boyle AL**. [Prevalence and predictors of intimate partner violence in a military urogynecology clinic](#). *Mil Med*. 2017;182(3):e1634-e1638.
- Manjelievskaia J, Brown D, Shao S, Hofmann K, Shriver CD, Zhu K.** [Benefit type and care source in relation to mammography screening and breast cancer stage at diagnosis among DoD beneficiaries](#). *Mil Med*. 2017;182(3):e1782-e1789.
- McLaughlin A, Colyer MH**, Ryan DS, et al. [Self-reported visual quality of life after combat ocular trauma](#). *Mil Med*. 2017;182(S1):239-242. Additional Walter Reed Bethesda authors: **Spiegelman A, Mazzoli RA**
- Meyer RM, **Miller CA, Coughlin DJ**, et al. [Glioblastoma recurrence, progression, and dissemination as a purely subdural gliosarcoma](#). *J Neurooncol*. 2017 Mar 13. [Epub ahead of print] Additional Walter Reed Bethesda authors: **Rymarczuk G, Szuflińska NS, Cirivello MJ, Theeler BJ, Dirks MS**
- Miles SM**, Hardy BL, Merrell DS. [Investigation of the microbiota of the reproductive tract in women undergoing a total hysterectomy and bilateral salpingo-oophorectomy](#). *Fertil Steril*. 2017;107(3):813-820.e1.
- Morgan MK, Hartzell JD, Blaylock JM.** [Sepsis mimicker in an human immunodeficiency virus-infected patient](#). *Mil Med*. 2017;182(3):e1861-e1863.
- Mula KN, Cassler NM, Dent M, Gratrix M.** [Chemical matricectomy successfully performed with a tympanic membrane phenol applicator kit](#). *Dermatol Surg*. 2017;43(3):462-464.
- Nadolsky K.** [It's what's on the inside that counts](#). *Obesity (Silver Spring)*. 2017;25(3):495.
- Nathan DE, Bellgowan JF, French LM**, et al. [Assessing the impact of post traumatic stress symptoms on resting state function networks in a military chronic mild traumatic brain injury sample](#). *Brain Connect*. 2017 Mar 19. [Epub ahead of print] Additional Walter Reed Bethesda authors: **Wolf JP, Oakes T, Mielke JB, Sham EB, Liu W, Riedy G**
- Onakomaiya MM, Kruger SE**, Highland KB, **Kodosky PN, Pape MM**, Roy MJ. [Expanding clinical assessment for traumatic brain injury and comorbid post-traumatic stress disorder: a retrospective analysis of virtual environment tasks in the computer-assisted rehabilitation environment](#). *Mil Med*. 2017;182(S1):128-136.
- Pan Q, Jampel HD, Ramulu P, et al. [Clinical outcomes of gamma-irradiated sterile cornea in aqueous drainage device surgery: a multicenter retrospective study](#). *Eye (Lond)*. 2017;31(3):430-436. Walter Reed Bethesda author: **Cute D**
- Pintauro M, Duffy A, Vahedi P, **Rymarczuk G**, Heller J. [Interspinous implants: are the new implants better than the last generation? A review](#). *Curr Rev Musculoskelet Med*. 2017 Mar 22. [Epub ahead of print]
- Pisano A, Helgeson M.** [Cervical disc replacement surgery: biomechanical properties, postoperative motion, and postoperative activity levels](#). *Curr Rev Musculoskelet Med*. 2017
- Rosko PJ, Kavanaugh MJ, **Boese ML**, Longwell JJ, Earley AS. [Rotational thromboelastometry \(ROTEM\) guided treatment of an Afghanistan viper envenomation at a NATO military hospital](#). *Clin Toxicol (Phila)*. 2017;55(3):229-230.
- Rymarczuk GN**, Harrop JS, Hilis A, Härtl R. [Should expandable TLIF cages be used routinely to increase lordosis?](#) *Clin Spine Surg*. 2017;30(2):47-49

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PUBLICATIONS, from page 13

Sadowski BW, Lane AB, Wood SM, Robinson SL, Kim CH. [High-value cost-conscious care: iterative systems-based interventions to reduce unnecessary lab testing](#). *Am J Med*. 2017 Mar 23. [Epub ahead of print]

Sheffield BM, Schuchman G, Bernstein JG. [Pre- and postoperative binaural unmasking for bimodal Cochlear implant listeners](#). *Ear Hear*. 2017 Mar 15. [Epub ahead of print]

Slebos DJ, Breen D, Coad J, et al. [Safety and histological effect of liquid nitrogen metered spray cryotherapy in the lung](#). *Am J Respir Crit Care Med*. 2017 Mar 30. [Epub ahead of print] Walter Reed Bethesda author: Browning R

Stinner DJ, Wenke JC, Ficke JR, et al. [Military and civilian collaboration: the power of numbers](#). *Mil Med*. 2017;182(S1):10-17. Walter Reed Bethesda author: Gordon W

Teng PN, Bateman NW, Wang G, et al. [Establishment and characterization of a platinum- and paclitaxel-resistant high grade serous ovarian carcinoma cell line](#). *Hum Cell*. 2017 Mar 1. [Epub ahead of print] Additional Walter Reed Bethesda authors: Oliver KE, Darcy KM, Hamilton CA, Maxwell GL, Conrads TP

Vasquez M, Cardarelli C, Glaser J, Murthi S, Stein D, Scalea T. [The ABC's of pancreatic trauma: airway, breathing, and computerized tomography scan?](#) *Mil Med*. 2017;182(S1):66-71.

Vlasov A, Kim WI. [The efficacy of two trabecular bypass stents compared to one in the management of open-angle glaucoma](#). *Mil Med*. 2017;182(S1):222-225.

Vlasov A, Ryan DS, Ludlow S, et al. [Corneal and corneoscleral injury in combat ocular trauma from operations Iraqi freedom and enduring freedom](#). *Mil Med*. 2017;182(S1):114-119. Additional Walter Reed Bethesda authors: Coggin A, Colyer MH

Volner K, Dunn B, Chang ET, et al. [Transpalatal advancement pharyngoplasty for obstructive sleep apnea: a systematic review and meta-analysis](#). *Eur Arch Otorhinolaryngol*. 2017;274(3):1197-1203. Additional Walter Reed Bethesda author: Brietzke SE

Will N, Whitehead MT, Meany HJ, Reilly BK. [A 6-year-old presenting with headache and post-auricular pain](#). *Am J Otolaryngol*. 2017;38(2):248-250.

Winn AE, Rivard SC, Gratrix ML. [Dermal piercing removal: searching for an optimal technique](#). *Dermatol Surg*. 2017 Mar 23. [Epub ahead of print] □

DARNALL MEDICAL LIBRARY Research and Scholarly Communication Support

Sarah Cantrell, Michele Mason-Coles, and Lyubov Tmanova, librarian, offer research support to Walter Reed Bethesda's biomedical community. They lead research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

Research and Scholarly Communication Classes ■ Building 5, Room 4011

DATABASE WORKSHOPS

PubMed: Intermediate to Advanced

27 APR 2017 | 1200 to 1300 | Bldg 5 (Heroes) Room 4011

Maximize your existing PubMed (MEDLINE) search skills and become a more-efficient researcher. In this workshop, you will advance your understanding of Medical Subject Headings (MeSH), the MeSH search builder, and PubMed's Topic-Specific Queries. We will teach you not only how to effectively search for information about drugs and diseases—but also how to craft more-complex searches for clinical and biomedical research. This class is perfect for individuals who are embarking on a literature review or for those who have complex clinical or research questions. Basic foundation in searching PubMed is recommended. [Click here to register](#).

Searching the Nursing Literature with CINAHL + JBI

11 MAY 2017 | 1200 to 1300 | Bldg 5 (Heroes) Room 4011

CINAHL (Cumulative Index to Nursing & Allied Health Literature) and the Joanna Briggs Institute (JBI) databases are two of the premier evidence-based nursing literature resources. Learn how to effectively search for pertinent journal articles, systematic reviews, evidence summaries, and recommended practices. [Click here to register](#).

NCBI Medical Genetics Resources

16 JUN 2017 | 1200 to 1300 | Bldg 6 Room 1369 The National Center for Biotechnology Information (NCBI) provides access to biomedical and genomic information. This workshop introduces NCBI molecular databases centered on human medical genetics and information on genetic tests and laboratories. [Click here to register](#).



RESEARCH WORKSHOPS

Writing Systematic Reviews

18 APR 2017 | 1200 to 1300 | Bldg 5 (Heroes) Room 4011

This workshop provides an overview of the purpose, structure, components, and writing process of systematic reviews. Attendees will become familiar with systematic review standards and guidelines and will explore opportunities for collaboration with librarians. [Click here to register.](#)

Designing a Compelling Scientific Presentation

28 APR 2017 | 1300 to 1400 | Bldg 5 (Heroes) Room 4011

This workshop will help you to structure and design your research presentation using the key components and elements of scientific presentation to communicate your research findings to your audience. [Click here to register.](#)

Research Data Management

13 JUN 2017 | 1200 to 1300 | Bldg 6 Room 1369

This workshop introduces a concept of data-driven research, research data management, and data management planning for

grant proposals. The research data life cycle, including data collection, processing methods, and analysis of qualitative and quantitative data will be discussed. Attendees will become familiar with data submission standards and DoD biomedical research and data policy. [Click here to register.](#)

Preparing Your Manuscript for Publication

20 JUN 2017 | 1200 to 1300 | Bldg 6 Room 1369

This workshop is centered on planning, writing, and submitting manuscripts for publication in biomedical journals. Students will be guided through the publication process, journal selection, and authorship guidelines and standards. The writing section of the workshop is centered on steps and tips for writing a compelling manuscript (title, abstract, introduction, methods/materials, results, and discussion). The manuscript submission process and review, copyright issues, research integrity, and DoD public access policy compliance will also be discussed. [Click here to register.](#)

CITATION MANAGEMENT WORKSHOPS

Managing Reference Citations with EndNote (Desktop/Standalone version)

25 APR 2017 | 1200 to 1300 | Bldg 5 (Heroes) Room 4011

This workshop will help you to develop basic skills in bibliographic management using EndNote standalone and web-based citation manager. You will learn how to create a reference library, collect reference citations from various biomedical literature databases, organize references, generate and format a bibliography, share your library with peers, connect with researchers, and write and cite using the Cite While You Write EndNote feature. [Click here to register.](#)

Managing Reference Citations with EndNote (Web version) 18

MAY 2017 | 1200 to 1300 | Bldg 5 (Heroes) Room 4011 This workshop will help you to develop basic skills in bibliographic management using EndNote Web citation manager. In this hands-on class, you will create an online account via the Darnall Medical Library and will create a reference library accessible anywhere/ anytime, collect citations from various biomedical literature databases, organize references, generate and format bibliographies, share your library electronically with peers, and insert references into a Word document. You will also be briefly introduced to EndNote Desktop. [Click here to register.](#)

QUICK TALK WORKSHOPS—45 MINUTES OR LESS!

Article Retrieval: What to do when Plan A Fails

21 APR 2017 | 1300 to 1345 | Bldg 5 (Heroes) Room 4011

8 JUN 2017 | 1200 to 1245 | Bldg 6 Room 1369

You have used the skills from our PubMed classes to create a search. Now you have a list of articles you want to read. The "Locate@Darnall" link is meant to take you straight to the article you want, but sometimes it does not work properly. This class will help you troubleshoot the common error messages you get when the Locate@Darnall link does not work. [Click here to register for 21 APR class.](#) [Click here to register for 8 JUN class.](#)

Keeping Up with the Literature

16 MAY 2017 | 1200 to 1245 | Bldg 5 (Heroes) Room 4011 Keeping up with current biomedical research can be overwhelming. Imagine having one single list of articles from your favorite journals,

newspapers, web sites, and blogs which you could peruse at your leisure. We will show you ways you can keep current by setting up search alerts and browsing your top journals in a mobile-friendly way. In just 45 minutes, you will learn all you need to know to get started! [Click here to register.](#)

Providing Health Information to Your Patients at the Point of Care 19

MAY 2017 | 1200 to 1245 | Bldg 5 (Heroes) Room 4011 Have patients mentioned their attempts to Google diagnosis or treatment information? In this workshop, participants will learn about free online patient health information resources that are vetted, reliable, and credible and about patient health information available in the library's clinical resources. Participants will learn tools to identify reliable health information for patients at the point of care. [Click here to register.](#)



WEB RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

Education Materials

- [Belmont Report](#)

The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.

- [Comparison of FDA and HHS Regulations](#)

The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.

- [The President's Council on Bioethics](#)

This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.

- [Clinical Trials.gov](#)

Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.

- [HHS Office for Human Research Protections](#)

HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.

- [HHS Office of Civil Rights](#)

HHS Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).

- [MedlinePlus](#)

MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.

- [Office for Human Research Protections \(OHRP\)](#)

OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.

- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)

HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.

- [Protocol Review](#)

HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.

- [Informed Consent](#)

HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to documentation.

- [Investigators](#)

HHS provides investigators guidance about emergency medical care and research.

- [Biological Material and Data](#)

HHS provides guidance and the law about research involving the use of biological material and data.

- [Vulnerable Populations](#)

HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)

- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)

- [Preambles to GCP Regulations](#)

- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)

- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)

- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)

- [Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products \(21 CFR Parts 50 and 56\)](#)

- [Informed Consent Elements \(21 CFR 50.25\(c\)\)](#)



*Walter Reed National Military Medical Center
Department of Research Programs*

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Mondays 1200–1300

Month	Dates Radiology Conference Room B015, Building 19, Basement
April	17 24
May	1 8 15 22
June	5 12 19 26
July	3 10 17 24 31
August	7 14 21 28



*The Department of Research Programs at
Walter Reed National Military Medical Center presents*

2017 RESEARCH AND INNOVATION MONTH *Be a research hero — and more.*

IMPORTANT DATES

Poster Display Week

☐ 01–05 May

All competition participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort will carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center (Walter Reed Bethesda) and its neighbors, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

☐ 03 May – Poster Competition I (Case Reports, Evidence-Based Practice, and Quality Improvement)

Finalists from non-research competition categories present their posters to judges in Building 9, East Wing. Award ribbons will be pinned next to the winning posters of each research competition category.

☐ 04 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)

Participants in this category will present their project posters for first, second, and third prizes in Building 9.

Research Symposia I and II

☐ 09–10 May

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slides on their work before judges in Memorial Auditorium, Building 2, third floor. Winners receive certificates and medallions. Also, winners of Poster Competitions I and II will present.

5th Annual Aware for All

☐ 16 May

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

Spring Research Summit

☐ 24 May

Research-related groups present slides, share information, and network about their work at Memorial Auditorium, Building 2, third floor.

***For details on Research and Innovation Month,
contact the Department of Research Programs:***

dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil

